

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Claim 36 is amended to address the minor issue noted paragraph "4" on page two of the Official Action. Accordingly, withdrawal of the claim rejection is respectfully requested.

The claims currently pending in this application are Claims 18-36, with Claim 18 being the only independent claim.

Independent Claim 18, and many of the dependent claims, are rejected based on the disclosure in U.S. Patent No. 5,511,551 to *Sano et al.* in view of the disclosure in U.S. Patent No. 5,031,630 to *Hirano et al.* That rejection is respectfully traversed for several reasons.

Independent Claim 18 defines a cuff apparatus for measuring blood pressure. The claimed cuff apparatus comprises a chassis, a hollow cylindrical airbag, a plurality of cushions provided in the airbag, and first and second microphones. The hollow cylindrical airbag is received in the chassis, and the inner wall of the airbag suppresses blood flow when compressed air is introduced into the airbag. The cushions in the airbag cause the airbag to remain in the inflated state before compressed air is introduced into the airbag. The first and second microphones are arranged to oppose each other. One of the microphones detects Korotkoff sounds at the right upper arm of the human body near arteries thereof when the right upper arm is inserted through and covered with the hollow cylindrical airbag and compressed air is introduced into the airbag. The other microphone detects Korotkoff sounds at the left upper arm of the human body near arteries thereof when

the left upper arm is inserted through and covered with the hollow cylindrical airbag and compressed air is introduced into the airbag.

The claimed cuff apparatus is advantageously constructed in a way that facilitates introduction of the compressed air in a relatively short time. At the same time, the cuff apparatus is relatively easy to handle and assemble. The opposing position of the two microphones allows the cuff apparatus to detect Korotkoff sounds (i.e., measure blood pressure) at both the left arm and the right arm near arteries thereof, thus providing a quite useful and versatile cuff apparatus.

Sano et al. discloses a blood pressure meter cuff specifically configured to detect pressure at an individual's finger. As the Official Action correctly notes, the cuff disclosed in *Sano et al.* does not include microphones that detect Korotkoff sounds.

To address the deficiency in *Sano et al.*, the Official Action refers to the disclosure in *Hirano et al.* of an automatic blood pressure measuring apparatus that includes several microphones for detecting Korotkoff sounds. For at least the reasons discussed below, it is respectfully submitted that no rationale exists for the modification proposed in the Official Action and so it would not have been obvious, based on the disclosures in *Sano et al.* and *Hirano et al.*, to construct a cuff apparatus having the features recited in Claim 18.

As mentioned above, *Sano et al.* describes a finger-type blood pressure meter cuff. Blood pressure measuring devices of this type measure blood pressure based on the oscillometric principal in which blood pressure is measured based on oscillations of the blood pressure or blood vessel. That is, the cuff is initially inflated to a pressure higher than the systolic blood pressure and is then reduced to below

the diastolic pressure over a period of time (e.g., about 30 seconds). When blood flow is nil (i.e., the cuff pressure exceeds the systolic pressure) or is unimpeded (i.e., the cuff pressure is below the diastolic pressure), the cuff pressure will be generally constant. When blood flow is present, but restricted, the cuff pressure, which is monitored by a pressure sensor, will vary periodically and synchronously with the cyclic expansion and contraction of the artery. That is, it will oscillate. Significantly, with this type of cuff, it is quite important that the cuff size be correct, as an undersized cuff can yield too high a pressure measurement whereas an oversized cuff can yield too low a pressure measurement. *Sano et al.* emphasizes this point in the background discussion at column 1, lines 38-63.

In contrast to the cuff disclosed in *Sano et al.*, *Hirano et al.* describes an arm-type blood pressure measuring apparatus that measures blood pressure by way of Korotkoff sounds. This cuff uses microphones to detect the Korotkoff sounds and then determine the blood pressure. With this type of device, the cuff is inflated until the artery is completely occluded. Upon slowly releasing the cuff pressure, blood begins to flow in the artery, and the turbulent flow creates a pounding sound or Korotkoff sound. The pressure at which this sound is first heard represents the systolic blood pressure. Eventually, after the cuff pressure is further released, no sound can be heard and this represents the diastolic blood pressure. This method of blood pressure measurement necessitates that it be possible to accurately detect Korotkoff sounds, which in turn requires the ability to accurately sense or determine blood flow. This type of blood pressure measurement has useful application when measuring blood pressure at the upper arm of an individual because of the presence of larger blood vessels in the arm which provide larger blood flow.

In contrast, the blood pressure meter cuff disclosed in *Sano et al.* is specifically constructed as a finger type blood pressure measuring cuff. Blood vessels in the fingers are relatively small, with quite little blood flow. Because of this, it is difficult to rely upon detection of Korotkoff sounds in order to measure blood pressure. It is for at least this reason that finger type blood pressure measuring cuffs such as disclosed in *Sano et al.* rely upon the oscillometric principal to measure blood pressure.

Considering that the blood pressure meter cuff disclosed in *Sano et al.* is specifically adapted for use as a finger-type blood pressure cuff, one of ordinary skill in the art would not have found it obvious to provide the disclosed blood pressure meter cuff with microphones for purposes of detecting Korotkoff sounds. That is, the relatively small blood vessels in the finger produce relatively little blood flow and thus hinder the ability to accurately determine blood pressure by detecting Korotkoff sounds. In addition, because the blood pressure meter cuff disclosed in *Sano et al.* is specifically adapted to use as a finger type blood pressure cuff, the blood pressure cuff is necessarily quite small, thus hindering the ability to provide the cuff with microphones for purposes of detecting blood pressure through detection of Korotkoff sounds.

For at least the foregoing reasons, it is respectfully submitted that one of ordinary skill in the art would not have found it obvious to provide *Sano et al.*'s. finger type blood pressure measuring cuff with microphones as disclosed in *Hirano et al.*

Even if such a modification was carried out, the result would not be the cuff apparatus defined in independent Claim 18. As noted above, Claim 18 recites that the first and second microphones are arranged in opposing relation to each other in

the hollow cylindrical airbag so that the first microphone detects Korotkoff sounds at the right upper arm of the human body when the right upper arm is inserted and covered with the hollow cylindrical airbag and when compressed air is introduced, and the second microphone detects Korotkoff sounds at the left upper arm of the human body when the left upper arm is inserted through and covered with the hollow cylindrical airbag and when compressed air is introduced.

The inflatable cuff disclosed in *Hirano et al.* includes a first set of sensing elements 18, 20, 22 and a second set of sensing elements 24, 26, 28. As discussed beginning in line 47 of column 3 and beginning in line 12 of column 7 of *Hirano et al.*, the first set of sensing elements 18, 20, 22 is arranged in the proximal end area (as seen with reference to the width direction of the cuff) of the cuff inner surface along the lengthwise direction of the cuff, and the second set of sensing elements is arranged in the middle area (as seen with reference to the width direction of the cuff) of the cuff inner surface along the lengthwise direction. The sensing elements 18, 20, 22 forming the first set are aligned with the sensing elements 24, 26, 28 of the second set. The sensing elements 18, 20, 22 of the first set detect the proximal arterial sounds transmitted from the artery to the proximal area of the cuff, while the sensing elements 24, 26, 28 forming the second set detect Korotkoff sounds transmitted from the artery to the middle area of the cuff. *Hirano et al.* describes that

Nowhere does *Hirano et al.* disclose that the sensing elements are arranged in a hollow cylindrical airbag in opposing relation to each other so that one sensing element detects Korotkoff sounds at a right upper arm of the human body while the other sensing element detects Korotkoff sounds at the left upper arm of the human body. *Hirano et al.*'s reason for employing two sets of sensing elements is quite

different. *Hirano et al.* describes that the sensing elements 18, 20, 22 forming the first set of sensing elements detect proximal arterial sounds, and the sensing element 18, 20, 22 that detects the sound of greatest magnitude is identified as the optimum first sensing element. Then, the Korotkoff sound detected by the second sensing element 24, 26, 28 that is aligned with the optimum first sensing element is selected as the optimum second sensing element. Thereafter, if the optimum second sensing element detects a sound within a specified time window (i.e., a time window that is opened a first time duration after the time of detection of the proximal arterial sound by the optimum first sensing element 18, 20 or 22 and is closed a second time duration after such time), such sound is collected as a Korotkoff sound.

It is thus apparent that *Hirano et al.* discloses plural sensing elements for a particular reason. If an ordinarily skilled artisan was somehow motivated to employ the plural microphones described in *Hirano et al.* in the finger-type cuff described in *Sano et al.* as suggested in the Official Action, there exists no rational for positioning such microphones in the manner recited in Claim 18. Certainly, *Hirano et al.* does not describe positioning the sensing elements in opposing relation to one another in a hollow cylindrical airbag so that one sensing element detects Korotkoff sounds at a right upper arm of the human body while the other sensing element detects Korotkoff sounds at the left upper arm of the human body. Further, there would be no reason to position the sensing elements in such a manner in order to achieve the objectives sought to be achieved by *Hirano et al.*

For at least the reasons set forth above, it is respectfully submitted that the claimed cuff apparatus recited in independent Claim 18, and the various dependent

claims, is patentably distinguishable over the disclosures contained in the applied documents.

The dependent claims define further distinguishing features and characteristics associated with the claimed cuff apparatus. As these claims are allowable at least by virtue of their dependence from allowable independent Claim 18, a further discussion of the distinguishing features set forth in the dependent claims is not set forth at this time.


Early and favorable consideration of this application is respectfully requested.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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